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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|-------------------|
| 09/981,845 | 10/18/2001 | Samy Ashkar | CMCC 779 | 7069 |
| 23579 | 7590 | 03/06/2003 | | |
| PATREA L. PABST HOLLAND & KNIGHT LLP SUITE 2000, ONE ATLANTIC CENTER 1201 WEST PEACHTREE STREET, N.E. ATLANTA, GA 30309-3400 | | | EXAMINER | DEBERRY, REGINA M |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1647 | |

DATE MAILED: 03/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|------------------------------|------------------------|---------------------|--|
| | 09/981,845 | ASHKAR ET AL. | |
| | Examiner | Art Unit | |
| | Regina M. DeBerry | 1647 | |

-- The MAILING DATE of this communication app ars on the cov r sheet with th correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 23 September 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-18 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) _____ is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)
4) Interview Summary (PTO-413) Paper No(s)
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, drawn to osteopontin-derived peptide, classified in class 530, subclass 300.
- II. Claims 8-16, drawn to the implant and method of coating implant with osteopontin, classified in class 424, subclass 422.
- III. Claim 17, drawn to a method of inducing new tissue formation at a site on a subject comprising administering osteopontin classified in class 424, subclass 1.33.
- IV. Claim 18, drawn to a method for promoting cell differentiation comprising administering a therapeutically effective amount of a peptide to a subject, classified in class 514, subclass 2.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. §806.06 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons: Groups I-II are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. The protein of Group I can be prepared by processes which are materially different from the implant of Group II, such as by

chemical synthesis, or by isolation and purification from natural sources. Additionally, the protein of Group I can be used in materially different methods other than coating the implant in Group II, such as in making antibodies.

Inventions I/III and I/IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group I can be used in a materially different process of using from the method of Group III such as screening assays to identify binding partners. In addition the method of Group IV can be practiced with another product such as a growth factor.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. §806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups II, III and IV are directed to methods that recite structurally and functionally distinct elements, are not required one for the other, and/or achieve different goals. Invention II requires coating an implant with osteopontin, which is not required by any of the other groups. Invention III requires inducing new tissue formation at a site on a subject comprising administering osteopontin, which is not required by any of the other groups. Invention IV requires promoting cell differentiation comprising administering a therapeutically effective amount of a peptide to a subject. Therefore, a search and examination of all methods in

one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and/or the subject matter is divergent.

Claim 1 is generic to a plurality of disclosed patentably distinct species (SEQ ID Nos) comprising SEQ ID Nos 7, 8, 9, 10, 11, 12, 13, 14 and 15. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 5 is generic to a plurality of disclosed patentably distinct species (integrins) comprising $\alpha v \beta 3$, $\alpha v \beta 5$, $4 \beta 1$, $2 \beta 1$, VCAM, ICAM, CD44 and V3Vx. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 6 is generic to a plurality of disclosed patentably distinct species (cells) comprising osteoprogenitor cells, tumor cells, macrophages, periosteal cells, endothelial cells, epithelial cells, eosinophils, stem cells, limited potential precursor cells, precursor cells, committed precursor cells, and differentiated cells. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 10 is generic to a plurality of disclosed patentably distinct species (SEQ ID Nos) comprising SEQ ID Nos 8 and 15. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, separate search requirements, and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on 9:00 a.m.-6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RMD

RMD
March 4, 2003

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER